

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 15.03.2017

Version number 9

Revision: 15.03.2017

Hazardous according to criteria of Australian Safety and Compensation Council

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** *Glaciosite*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*
- **Application of the substance / the mixture** *Dental filling material*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Australien contact and address:*  
*VOCO Australia Pty Ltd.*  
*Suite 406-408, 251 Oxford Street,*  
*Bondi Junction, NSW 2022*
- **Further information obtainable from:** *Australia 02 9369 1770*
- **1.4 Emergency telephone number:** *Australia: 131126*

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Skin Sens. 1 H317 May cause an allergic skin reaction.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*As a medical device the product is not subject to labelling regulations under 1272/2008/EC.*
- **Hazard pictograms** *GHS07*
- **Hazard statements**  
*May cause an allergic skin reaction.*
- **Precautionary statements**  
*Wear protective gloves / protective clothing.*  
*If skin irritation or rash occurs: Get medical advice/attention.*  
*IF ON SKIN: Wash with plenty of water.*  
*Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **Additional information:**  
*Contains Benzotriazole derivate. May produce an allergic reaction.*
- **2.3 Other hazards** *Use only for intended scope of application*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**

1565-94-2	<i>BIS GMA</i> <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</i>	<i>10-25%</i>
109-16-0	<i>Triethylene glycol dimethacrylate</i> <i>Skin Sens. 1, H317</i>	<i>2.5-5%</i>

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#### **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** For dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See storage instructions on package
- **7.3 Specific end use(s)** No further relevant information available.

#### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.

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**· Protection of hands:**

Protective gloves

**· Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**· Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

**· 9.1 Information on basic physical and chemical properties****· General Information****· Appearance:**

<b>Form:</b>	Pasty
<b>Colour:</b>	According to product specification
<b>Odour:</b>	Characteristic

**· pH-value:** Not determined.**· Change in condition**

**Melting point/Melting range:** Undetermined.  
**Boiling point/Boiling range:** Undetermined.

**· Flash point:** Not applicable.**· Self-igniting:** Product is not selfigniting.**· Danger of explosion:** Product does not present an explosion hazard.**· Density:** Not determined.**· Solubility in / Miscibility with water:** Not miscible or difficult to mix.**· Viscosity:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.

**· 9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

**· 10.1 Reactivity** No further relevant information available.**· 10.2 Chemical stability****· Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.**· 10.3 Possibility of hazardous reactions** No dangerous reactions known.**· 10.4 Conditions to avoid** No further relevant information available.**· 10.5 Incompatible materials:** No further relevant information available.**· 10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

**· 11.1 Information on toxicological effects****· Acute toxicity** Based on available data, the classification criteria are not met.**· Primary irritant effect:****· Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>                    |                 |
| · <b>ADG, ADN, IMDG, IATA</b>              | Void            |
| · <b>14.2 UN proper shipping name</b>      |                 |
| · <b>ADG, ADN, IMDG, IATA</b>              | Void            |
| · <b>14.3 Transport hazard class(es)</b>   |                 |
| · <b>ADG, ADN, IMDG, IATA</b>              |                 |
| · <b>Class</b>                             | Void            |
| · <b>14.4 Packing group</b>                |                 |
| · <b>ADG, IMDG, IATA</b>                   | Void            |
| · <b>14.5 Environmental hazards:</b>       |                 |
| · <b>Marine pollutant:</b>                 | No              |
| · <b>14.6 Special precautions for user</b> | Not applicable. |

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- |  |                        |
|--|------------------------|
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | <i>Not applicable.</i> |
| · <b>UN "Model Regulation":</b>  | <i>Void</i>            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Australian Inventory of Chemical Substances**

*All ingredients are listed.*

- **Directive 2012/18/EU**  
· **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*

**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Department issuing SDS:** *Scientific department*

- **Contact:** *Tel.: +49 (0)4721-719-0*

- **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

*Skin Sens. 1: Skin sensitisation – Category 1*

- **\* Data compared to the previous version altered.**

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